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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,198	10/16/2000	Douglas A. Collins	COP1002	2250

7590

12/03/2003

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EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/690,198

Applicant(s)

COLLINS ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-154 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,12-15,18,20,24,49-51,55,56,60,61,111,112 and 121-154 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,6,8,10,11,16,17,19,21-23,25-48,52-54,57-59,62-110 and 113-120.

### **DETAILED ACTION**

Amendment filed on September 15, 2003 has been entered.

Claims 113 -120 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8. claims 2,4,6,8,10-11,16,19,21-23,25-48,52-54,57-59,62-110 are withdrawn because they do not read on the elected species.

Claims 1,3,5,7,9,12-15, 18, 20, 24, 49-51, 55-56, 60-61, 111-112, 121-154 are under consideration as they read on the elected species. Claim 18 depends on the non-elected species.

Any rejection or objection that is not addressed in this Office Action is considered obviated in view of Applicants' amendments and arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Double Patenting***

Claims 1,3,5,7,9,12-15,18,20,24,49-51,55-56,60-61, 121-154 stand provisionally rejected under the judicially created doctrine of double patenting over claims 1-28 of copending Application No. 10/027,593 for the reasons of record. Applicant's intention to file a Terminal Disclaimer is noted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 123 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "synthetics" renders the claim indefinite, because it is not clear to what type of compounds is applicant referring.

***Claim Rejections - 35 USC § 102***

Claims 1, 3,5,12-13,15,18,20,24,49-51,55,56,111-112, 123-126, 128-136, 142-154 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al US Patent 5,428,023 (Russell-Jones I).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. In response to applicant's argument that the instant claims are directed to injectable compositions, Examiner states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the compositions of Russell-Jones I meets all elements of the instant claims. Russell-Jones I teaches complexation of Luteinizing hormone-releasing hormone (LHRH) which is a well-known chemotherapeutic agent (also known as Leuprolide) used for treatment of advanced prostatic cancer. The formulation of Russell-

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Jones I is prepared in a Bovine Serum Albumin solution which is a pharmaceutically acceptable carrier. Furthermore, the reference teaches the use of conventional preservatives and carrier systems (see col 4, lines 22-60; col 5-7; claims 1,3,8).

Therefore, Russell-Jones meets all components of the instant claims.

Claims 1, 3,5,7,9,12-13,15,18, 20, 24,49-51,55,56,61,111-112, 123-126, 128, 133-137, 141-145, 147, 152-154 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al (Bioconjugate Chem 1995, 6, 459-465) (Russell-Jones II) or Pathare et al (Bioconjugate Chem 1996, 7, 217-232).

Similarly to the reasoning set forth above, Russell-Jones II and Pathare meet the limitation of the instant compositions. Thus, they also anticipate the intended use thereof. Specifically, Russell-Jones II prepares his final preparation in buffer solution. Pathare prepares his final preparation in a Tris/NaCl Buffer solution after eluting and purifying his product. These buffer system fall within the scope of the instantly claimed pharmaceutically acceptable carriers (see page 462, 4<sup>th</sup> para.). Therefore, Russell-Jones II and Pathare anticipate the limitations of the instant claims.

Claims 1,3,5,7,9,12-15, 18, 20, 24, 49-51, 55-56, 60-61, 111-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pathare et al in view of Grissom et al US Patent 6,315,978.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

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1986). In the instant case all elements of the instant claims are taught by the combined references as discussed in previous Office Action. Accordingly, the rejection is proper and here by maintained for the reasons of record.

Claims 1,3,5,7,9,12-15, 18, 20, 24, 49-51, 55-56, 60-61, 111-112, 121-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pathare et al in view of Grissom et al US Patent 6,315,978 as applied to claims 1,3,5,7,9,12-15, 18, 20, 24, 49-51, 55-56, 60-61, 111-112 and further in view of Habberfield et al US Patent 5,574,018 and Remington: 19<sup>th</sup> edition.

The combined teachings of Pathare and Grissom fail to specifically teach the use of preservatives, surfactants.

Habberfield provides the addition of all suitable excipients in Vitamin B12 bioconjugates such as surfactants, preservatives solublizers etc.. for preparation of intravenous formulations (see col 7, lines 4-15; col 8, lines 9-26).

Remington further provides for the use of aqueous or non-aqueous vehicles suitable for intravenous administration. Such vehicles employ sodium chloride, polyethylene glycols and various types of suitable oils, and preservatives. (see pages 1527-1529, 1561). Therefore, employing them for their own intended use is conventional in the art.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to prepare a bioconjugate of Vitamin B 12 with a Doxorubicin as taught by the teachings of Pathare and Grissom, for the reasons of record, and further employ suitable compoenents such as preservatives, PEGs and oils for their own

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intended use because as taught by Habberfield the ordinary skill in the art would have had a reasonable expectation of success in making safe and stable intravenous formulations of a vitamin B12 bioconjugates.

***Conclusion***

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The



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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200